### **REMARKS**

The Final Office Action of September 22, 2008, has been received and reviewed. Applicants respectfully request that the claims be amended as previously set forth. All amendments are made without prejudice or disclaimer. No new matter has been presented. Reconsideration is respectfully requested.

#### Interview

The applicants' representative would like to thank the Examiner for the courtesy extended them during the telephone interview of November 19, 2008. The interview was very helpful to the applicants and their representative in gaining an understanding of the Examiner's concerns. At the interview, the rejection made in the Final Office Action of September 22, 2008 regarding claim 15 was discussed as were the Examiner's and applicants perspectives with respect to the rejection. As discussed at the interview, applicants are amending the application as previously set forth in an effort to remove outstanding issues and otherwise expedite prosecution. If the Office believes that further comments are necessary or desired describing the interview, the Examiner is kindly requested to contact applicants' undersigned attorney, and further detail will be promptly provided.

# Rejection under 35 U.S.C. § 102(b)

Claim 15 stands rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Jasinski et al. (<u>Bulletin de la Societe Royale des Sciences de Leige</u>, 68(5-6): 323) in light of Jasinski et al. (<u>The Plant Cell</u>, 13: 1095-1107), and the sequence report appended to the Office Action of February 26, 2008. Applicants respectfully traverse the rejection as hereinafter set forth.

Applicants note that a claim is only anticipated if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully assert that claim 15 as amended cannot be anticipated by the cited references, because they do not teach each and every element of amended claim 15. Claim 15, as amended, recites "An isolated polynucleotide sequence comprising a sequence having at least 91% identity

to the polynucleotide sequence of SEQ ID NO:1." Applicants respectfully submit that Jasinski cannot anticipate amended claim 15 as Jasinski does not teach "a sequence having at least 91% identity to the polynucleotide sequence of SEQ ID NO:1." Applicants further submit that the sequence report appended to the Office Action of February 26, 2008 also does not show "a sequence having at least 91% identity to the polynucleotide sequence of SEQ ID NO:1." Consequently, applicants respectfully submit that neither Jasinski nor the sequence report appended to the Office Action of February 26, 2008 can anticipate claim 15 as amended. In view of the foregoing, applicants respectfully request the withdrawal of the rejection of claim 15 under 35 U.S.C. § 102 and reconsideration of same.

## Rejections under 35 U.S.C. § 103(a)

Claims 1-13, 15-19, and 22-24 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Rea *et al.* (WO 98/21938; claims 1-13, 15-19, and 22-24); and Theodoulou (Biochemica et Biophysica Acta, 1465: 79-103) in view of Dudler *et al.* (J. Biol. Chem., 267(9): 5582-5588) in further view of Sidler *et al.* (The Plant Cell, 10:1623-1636; claims 1-13, 15-19, and 22-24). Applicants respectfully traverse the rejections as hereinafter set forth.

### Rea

The Office asserts, at pages 4 and 5 of the Final Office Action mailed September 22, 2008, that applicants' specification at paragraph 0043 indicates that production and secretion can be equivalent in their meaning. Applicants respectfully disagree.

"Enhanced production" is defined at paragraph 0043 of the Specification as published; to wit:

By the term "to enhance the production" it is meant that the level of one or more metabolites may be enhanced by at least 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% or at least 100% relative to the untransformed plant which was used to transform with an expression vector comprising an expression cassette further comprising a gene coding for a transporter or an ABC-transporter.

"Enhanced secretion" is defined at paragraph 0032 of the Specification as published; to wit:

An "enhanced secretion of at least one secondary metabolite" means that there exists already a detectable secretion of the secondary metabolite(s) in the extracellular medium of the plant cell culture and that an increase of the secondary

metabolite(s) can be measured by at least 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90% or more than 90% compared to basal secretion by the untransformed plant cell culture. An "enhanced secretion" does not necessarily mean that there is a higher production, it can also mean that there exists the same level of production but that the secretion is enhanced.

Thus, the Specification clearly delineates production and secretion as separate processes. Applicants respectfully submit that the sections of paragraph 43 cited by the Examiner indicate that production and secretion <u>may</u> be linked one after the other to increase secretion, but that this is not necessarily so.

The Examiner cites to the following sentence of paragraph 0043: "[a]n enhanced production of a secondary metabolite can result in a detection of a higher level of secondary metabolites in the plant, for example in the vacuole." Applicants note the use of the words: "can result." Applicants respectfully submit that this describes one of many possible outcomes when increased production is combined with a second separate process. In the instance described in the cited sentence, increased production in the cytosol is combined with the separate process of increased transport into the vacuole. Further, there is nothing in the cited sentence to indicate that such a combination will always the be case, and, as would be understood by one of ordinary skill in the art, increased production and increased sequestration in the vacuole are separate and divorcable processes.

The Examiner also cites to the following sentence of paragraph 0043: "[i]n another embodiment, the enhanced production of at least one secondary metabolite leads to an enhanced secretion." Applicants note the use of the words: "in another embodiment." Applicants respectfully submit that this describes an additional one of many possible outcomes when increased production is combined with a second separate process. In the instance described in the cited sentence, increased production in the cytosol is combined with the separate process of increased secretion. Further, there is nothing in the cited sentence to indicate that such a combination will always the be case, and, as would be understood by one of ordinary skill in the art, increased production and increased secretion are separate and divorcable processes. This is borne out by the last sentence of paragraph 0032; to wit: "[a]n 'enhanced secretion' does not necessarily mean that there is a higher production, it can also mean that there exists the same level of production but that the secretion is enhanced."

In view of the foregoing, applicants respectfully submit that the Specification, as would be understood by one of ordinary skill in the art, describes separate process of "production" and "secretion," each of which may be combined with each other or with other discrete processes such as sequestration. Consequently, applicants respectfully submit that the Office misconstrues the teachings of the Specification when it asserts that secretion and production can be equivalent in their meaning.

The Office asserts that Rea teaches that the sequestration of a metabolite from the cytosol protects it from oxidation, and thus, the secretion to the vacuole will result in enhanced production as recited in the claim. Final Office Action of September 22, 2008 at page 4. First, applicants note that sequestration to the vacuole is not secretion as defined by the Specification, which requires that it be to the extracellular milieu. Second, applicants respectfully submit that there is nothing in Rea that teaches or suggests that the increased sequestration of the secondary metabolite to the vacuole by the GS-X transporter is related in any fashion to increased production. Rea simply shows that when a functional copy of GS-X is supplied, that proper transport to the vacuole occurs. Consequently Rea only teaches that GS-X (an ABC transporter) behaves like a transporter and moves its substrate from one location to another. To conclude that Read thus increases the production of the substrate is to read more into the art than it actually teaches. In fact, the production of GS-X, while leading to increased transport into the vacuole, may have no effect at all on the production of its substrate, and Rea teaches nothing to suggest otherwise.

In view of at least the foregoing, applicants respectfully request the withdrawal of the rejections of claims 1-13, 15-19, and 22-24 under 35 U.S.C. 103(a) in view of Rea and reconsideration of same.

### Theodoulou, Dudler, and Sidler

In the Final Office Action of September 22, 2008 at page 6, the Office reiterates its comments regarding the definition of enhanced production and enhanced secretion. In response, applicants incorporate by reference herein the remarks directed to the definitions of production and secretion made *supra*.

The Office further asserts that applicants' last response failed to respond to the Office's

assertion that one of ordinary skill would have read the results of Sidler and understood that auxin could also have been the secondary metabolite given the common knowledge in the filed. Final Office Action of September 22, 2008 at pages 5 and 6. In the Office Action of February 26, 2008, the Office asserts that "the prior art (Sidler) suggests that AtPGP1 transports a regulator involved in light dependent hypocotyls elongation, and speculates that that it may be a peptide. However, one must also consider what is well known in the art, that hypocotyl elongation is a response to auxin, which is a secondary metabolite."

Applicants note that the Office has provided no evidence of it's assertion that one of ordinary skill in the art would have concluded that the hypocotyl elongation is a response to auxin. Applicants note that the Office is subject to the Administrative Procedures Act and all conclusions must be based upon evidence of record. *See*, *e.g.*, <u>Dickinson v. Zurko</u> 527 U.S. 150 (1999); and <u>In re Sang-Su Lee</u>, 277 F.3d 1338 (C.A.Fed.,2002). Without evidence to support the assertion of the Office, such assertions should be ignored as merely Examiner argument. Further, the Sidler teaches that the substrate of the AtPGP1 transporter is likely a peptide. This is in direct contravention to the unsupported assertion of the Examiner that one of ordinary skill in the art would have considered auxin as the substrate.

Even if auxin were transported by AtPGP1 and was responsible for the hypocotyl elongation (which the applicants respectfully submit the Office has not shown), there is nothing in the art cited that would suggest that the increased hypocotyl elongation is due to increased production of auxin as opposed in increased secretion. Applicants respectfully submit that better secretion of auxin, absent increased production, might be responsible for the increased hypocotyl elongation described by Sidler. However, the prior art provides no indication, one way or another, in regards to increased production and any assertion that increased production has indeed occurred is no more than unsupported speculation on the part of the Office.

In view of at least the foregoing, applicants respectfully request the withdrawal of the rejections of claims 1-13, 15-19, and 22-24 under 35 U.S.C. 103(a) in view of Theodoulou, Dudler, and Sidler and reconsideration of same.

#### **ENTRY OF AMENDMENTS**

Pursuant to 37 C.F.R. § 1.116, applicants respectfully submit that the amendments

presented herein should be entered as the amendments are made to expedite prosecution, are

believed to remove issues for appeal, and place the application in condition for allowance.

Applicants respectfully note that, as indicated at MPEP § 714.13(III), the Examiner is

required to give the proposed amendments sufficient consideration to determine whether the

claims are in condition for allowance and/or whether the issues on appeal are simplified.

Applicants respectfully submit that the amendments avoid the rejections set forth in the Final

Office Action, raise no issues of new matter, present no issues requiring further consideration or

search, and do not present any additional claims. If the Examiner determines that the

amendments do not place the application in condition for allowance, entry is respectfully

requested as they remove issues for appeal. As such, the applicants respectfully request that the

amendments presented herein be entered and a Notice of Allowance issued.

**CONCLUSION** 

In light of the above amendments and remarks, applicants respectfully request reconsideration of the application. If questions remain after consideration of the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Office is kindly requested to contact applicants' attorney at the address

or telephone number given herein.

Respectfully submitted,

Daniel J. Morath, Ph.D. Registration No. 55,896

Attorney for Applicants

TRASKBRITT, P.C.

P.O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: 801-532-1922

Date: November 21, 2008